APPENDIX

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SARAGOVI et al.
Title:	COMPOUND TARGETED FOR SPECIFIC CELLS WITH REDUCED SYSTEMIC TOXICITY
Appl. No.:	10/600,623
Filing Date:	June 20, 2003
Examiner:	Brandon J. Fetterolf
Art Unit:	1642
Confirmation Number:	7195

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF EXPERT UNDER 37 C.F.R. § 1.132

Dear Sir:

I, Mark I. Greene, M.D., Ph.D., F.R.C.P., hereby declare that:

1. I hold a M.D., Ph.D. degree from the University of Manitoba. My doctorate research was on Immunology. I have 30 years of experience and active scientific research activity, and

numerous publications in the field of Immunology. A curriculum vitae is attached herewith as Exhibit A.

2. I have reviewed and understand the application and the invention disclosed in the above-identified patent application ("the '623 application").

3. I have reviewed and understand the Office Action mailed September 1, 2006. I am submitting this declaration attest to the knowledge of one of ordinary skill in the art at the time of the earliest effective filing date (December 21, 2000) of the '623 application.

4. The fields of monoclonal antibodies, the techniques for their conjugation as well as site-directed immunotherapy were well-developed arts. The general knowledge in the art was that antibodies were structurally well-characterized. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional. Methodology to conjugate small molecules via linkers was known in the art. This is a mature technology where the level of skill is high and advanced. Further, receptor-mediated endocytosis was a known biological mechanism for antibody-receptor complexes.

5. Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well-defined structural characteristics of antibodies, the functional characteristics of antibody binding, and the fact that the antibody technology is well-developed and mature, one of skill in the art would have recognized that the spectrum of monoclonal antibodies which bind to p75, TrKA and IGF-1R polypeptide were implicitly disclosed in the specification as filed. The disclosure three individual single species of antibody-based chemotherapeutic agents directed to p75, TrKA and IGF-1R polypeptide on the surface of a tumor cell, including a drug resistant tumor cell provide support for three relevant genus as an ordinary artisans could predict the operability in the invention of any species other than the species disclosed. That is, one of skill in the art would recognize that monoclonal antibody conjugates that recognize the same or other

determinants on p75, TrKA, or IGF-1R polypeptide on the surface of the tumor cells would be internalized to affect cytotoxicity. Determination of the classes of monoclonal antibodies-conjugates which bind to p75, TrKA or IGF-1R polypeptide on the surface of a tumor cell, including a drug resistant tumor cell, could be readily determined with a high probability of success by techniques well know in the art at the time the application was filed.

6. Monoclonal antibodies which bind to p75, TrKA and IGF-1R polypeptide can be made with a high rate of success from readily available starting materials without undue experimentation (*i.e.*, mice; p75, TrKA and IGF-1R polypeptide antigens; and myeloma cells).

7. I declare further that all statements made in this Declaration of my own knowledge are true, that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent that may issue from the present application.

Respectfully submitted,

Mark I. Greene
EXPERT
Date: _____ 2/26/2007

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Date of Birth: August 3,1948

Education:

1966-1968	University of Manitoba, Canada
1968-1972	M.D. University of Manitoba, Canada
1973-1976	F.R.C.P. Fellow of the Royal College of Physicians (Canada), Internal Medicine
1973-1977	Ph.D.University of Manitoba (Immunology)

Internship and Residencies:

1972-1973	Intern, Health Sciences Centre, Winnipeg, Canada
1973-1976	Resident, Health Sciences Centre, Winnipeg, Canada

Postgraduate Training and Fellowship Appointments:

1973-1975	Medical Research Council Fellowship, (MRC) Canada
1976-1978	Medical Research Council Fellowship, Boston
1976-1977	Research Fellow in Pathology, Harvard Medical School, Boston, Massachusetts

Faculty Appointments:

1977-1978	Instructor in Pathology, Harvard Medical School
1978-1980	Assistant Professor in Pathology, Harvard Medical School
1980-1985	Associate Professor of Pathology, Harvard Medical School
1982-1985	Associate Professor of Immunology, Department of Cancer Biology, Harvard University
1984-1986	Professor of Medicine, Head: Rheumatology/Immunology, Tufts University
1986-present	Director, Division of Immunology, Department of Pathology
	Professor of Pathology, University of Pennsylvania
1987-present	Associate Director for Fundamental Research, Cancer Center, University of Pennsylvania
1989-present	John Eckman Professor of Medical Sciences, Department of Pathology and Laboratory Medicine, University of Pennsylvania
1993-present	Vice Chair of Pathology, Division of Immunology and Experimental Pathology, University of Pennsylvania

Hospital and Administrative Appointments:

1980-1986	Consultant in Medicine, Dana Farber Cancer Centre, Boston
1986 to present	Hospital of the University of Pennsylvania

Licensure:

1973	Canadian License Registration (Manitoba)
1976	Massachusetts License Registration (38692)

1976 Fellow of the Royal College (FRCP)
1985 Pennsylvania (M.D.-033875-E)

Awards, Honors and Membership in Honorary Societies:

1966	Memorial Scholarship
1966	Sir Sam Steele Memorial Scholarship
1966	Actuarial Award
1966	University of Manitoba Scholastic Award
1966	Mathematic Association Prize
1973-1978	Medical Research Council Fellowship Award
1982	American Cancer Society Faculty Award
1985	American Society for Clinical Investigation
1985-1987	Focused Giving Award, Johnson & Johnson
1986	Lotte Strauss Award
1988-1993	Markey Trust Award-Receptor Biology
1988-1990	Trustee: Leukemia Society of America
1989	Councilor-American Society for Clinical Investigation
1989	John Eckman Professor of Medical Sciences
1991-1992	John Guggenheim Fellow
1991-1992	American Cancer Society Annual Scientific Award
1993-1996	Human Frontiers Award
1994	Bride's Magazine: Cancer Research Award
1994	Dean's Award
1995	Interurban Clinical Club
1996	Capcure Award
1996	American Association of Physicians (AAP)
1998	Stanley N. Cohen Biomedical Research Award
1998	Abramson Family Cancer Research Award
1999	Newton Abraham Professor-Oxford University (2002-2003)
2002	Ashmolean Society
2003	Master of Arts (Hon) Oxford University
2006	Allyn Taylor Prize in International Medicine

Major Committee Assignments (National and Regional):

1975	RH Institute Awards Committee, Canada
1978	British Society of Immunology
1980	American Association Immunologists
1982	American Association of Pathologists
1982-1985	Massachusetts Medical Association
1986	Chairman; Department of Physiology Chair Search Committee
1989	Chairman; Structural and Molecular Biology at the University of Pennsylvania-Review Committee
1989	Howard Hughes Advisory Committee-University of Pennsylvania
1995-1999	Howard Hughes Review Committee
1996-1999	NIH-NIDCD, Board of Scientific Counselors
2001- 2005	Scientific Advisor- Roswell Park Memoral Cancer Institute
2001- present	Scientific Advisor- Breast Cancer program-MD Anderson
2000-2005	Riken Institute, Board of Scientific Advisors

Editorial Positions:

Journal of Immunology, ad hoc reviewer
Journal of Experimental Medicine ad hoc reviewer
Cell , ad hoc reviewer
Nature, ad hoc reviewer
Science, ad hoc reviewer
Cellular Immunology-Editorial Board- through 1998
Immunologic Research-Editorial Board- present
EMBO , ad hoc reviewer
DNA & Cell Biology-Editor in Chief, 1990-Present
Journal of Mammary Gland Biology and Neoplasia Editorial board-
presen Experimental and Molecular Pathology- Senior Editor, 2000-Present
Pathobiology -Editor, 1990-1998

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3. Fujimoto, S., Greene, M.I. and Sehon, A.: Regulation of the immune response to tumor antigens. I. Immunosuppressor T cells in tumor-bearing host. Journal of Immunolology, 116(3):791-799, 1976.

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5. Greene, M.I., Fujimoto, S. and Sehon, A.: Regulation of the immune response to tumor antigens. III. Characterization of thymic suppressor factor(s) produced by the tumor-bearing host. Journal of Immunology, 119(2):757-764, 1977.

6. Greene, M.I., Pierres, A., Dorf, M.E. and Benacerraf, B.: The I-J subregion codes for determinants on suppressor factor(s) which limit the contact sensitivity response to picryl chloride. Journal of Experimental Medicine, 146:293-296, 1977.

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10. Bach, B.A., Sherman, L., Benacerraf, B. and Greene, M.I.: Mechanisms of the regulation of cell-mediated immunity. II. Induction and suppression of delayed-type hypersensitivity to azobenzenearsonate-coupled syngeneic cells. Journal of Immunology, 121(4):1460-1468, 1978.

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23. Greene, M.I., Sy, M.S., Kripke, M. and Benacerraf, B.: Impairment of antigen-presenting cell function by ultraviolet radiation. Proc. Natl. Acad. Sci. (USA), 76(12):6591-6595, 1979.

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determinants the expression of which is linked to heavy-chain allotype linkage group of genes. Journal of Experimental Medicine, 149:1084-1098, 1979.

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